WE CLAIM:

1. A controlled release pharmaceutical composition of tamsulosin, the composition comprising:

(a) a spheroid core comprising:

i. tamsulosin,

ii. about 10% to about 45% w/w of a spheronizing agent,

iii. one or more of rate controlling polymers, and;

(b) an enteric coating over the spheroid core.

2. The composition of claim 1, wherein the tamsulosin comprises free base, pharmaceutically acceptable salts and isomers of tamsulosin.

3. The composition of claim 2, wherein the pharmaceutically acceptable salts of tamsulosin comprise one or more of hydrochloride, hydroiodide, hydrobromide, and hydrogen fumarate..

4. The composition of claim 3, wherein the pharmaceutically acceptable salt of tamsulosin is a hydrochloride.

5. The composition of claim 1, wherein the composition comprises a concentration from about 0.03% to about 0.33% by weight of tamsulosin.

6. The composition of claim 1, wherein the spheronizing agent is microcrystalline cellulose.

7. The composition of claim 1, wherein the rate controlling polymer comprises one or more of enteric polymers, water insoluble polymers, water soluble polymers, alkaline metal salts of a higher fatty acid, waxes, and mixtures thereof.

8. The composition of claim 1, wherein the composition comprises from about 20% to about 90% by weight of rate controlling polymers.

9. The composition of claim 7, wherein the enteric polymer comprises one or more of hydroxylpropylmethyl cellulose phthalate, cellulose acetate phthalate, methacrylic acid and ethyl acrylate copolymer.

10. The composition of claim 9, wherein the enteric polymer comprises one or more of methacrylic acid and ethyl acrylate copolymer.

11. The composition of claim 7, wherein the wax comprises one or more of hydrogenated vegetable oils, esters of long chain fatty acids, long chain fatty acids, and mixtures thereof.

12. The composition of claim 11, wherein the wax is glyceryl monostearate.

13. The composition according to claim 11, wherein the wax is stearic acid.

14. The composition of claim 7, wherein the water soluble polymer comprises one or more of polyvinylpyrrolidone, hydroxypropyl cellulose, carboxymethylcellulose sodium, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, methyl cellulose, and mixtures thereof.

15. The composition of claim 7, wherein the water insoluble polymer comprises one or more of ethyl cellulose, cellulose acetate, methacrylic acid-acrylic acid copolymers with quaternary ammonium groups, and mixtures thereof.

16. The composition of claim 7, wherein the alkaline metal salts of higher fatty acid comprise one or more of magnesium stearate, zinc stearate, calcium stearate, and mixtures thereof.

17. The composition of claim 16, wherein the alkaline metal salt of higher fatty acid is magnesium stearate.

18. The composition of claim 1, wherein the spheroid core includes one or more of pharmaceutically acceptable excipients.

19. The composition of claim 18, wherein the pharmaceutically acceptable excipients include plasticizers, diluents, colorants, and flavoring agents.

20. The composition of claim 1, wherein the enteric coating layer comprises one or more of hydroxypropyl methylcellulose phthalate, polyvinyl phthalate, cellulose acetate phthalate, copolymers of acrylic and methacrylic acid, and mixtures thereof.

21. The composition of claim 20, wherein the enteric coating includes one or more of alkalizing agents, plasticizer, tack-modifiers and opacifiers.

22. The composition of claim 1, wherein the composition comprises capsules, sachets, and tablets.

23. A process for the preparation of a controlled release pharmaceutical composition of tamsulosin, the process comprising:

(a) granulating tamsulosin, spheronizing agent and one or more rate controlling polymers to obtain a granulating mixture,

(b) extruding the granulated mixture to obtain extrudates,

(c) spheronizing the extrudates to obtain spherical cores,

(d) drying the spheroid cores; and

(e) coating the spheroid cores with an enteric polymer.

24. The process of claim 24, wherein the tamsulosin comprises free base, pharmaceutically acceptable salts and isomers of tamsulosin.

25. The process of claim 24, wherein the pharmaceutically acceptable salts of tamsulosin comprise hydrochloride, hydroiodide, hydrobromide, and hydrogen fumarate.

26. The process of claim 25, wherein the pharmaceutically acceptable salt of tamsulosin is a hydrochloride.

27. The process of claim 23, wherein the pharmaceutical composition comprises a concentration of about 0.03% to about 0.33% by weight of tamsulosin.

28. The process according to claim 23, wherein the spheronizing agent is microcrystalline cellulose.

29. The process of claim 23, wherein the rate controlling polymer comprises one or more of enteric polymers, water insoluble polymers, water-soluble polymers, alkaline metal salts of a higher fatty acid, waxes, and mixtures thereof.

30. The process of claim 23, wherein the pharmaceutical composition comprises a concentration of about 20% to about 90% by weight of rate controlling polymers.

31. The process of claim 29, wherein the enteric polymer comprises one or more of hydroxylpropylmethyl cellulose phthalate, cellulose acetate phthalate, methacrylic acid and ethyl acrylate copolymer.

32. The process of claim 31, wherein the enteric polymer comprises one or more of methacrylic acid and ethyl acrylate copolymer.

33. The process of claim 29, wherein the wax comprises one or more of hydrogenated vegetable oils, esters of long chain fatty acids, long chain fatty acids, and mixtures thereof.

34. The process of claim 33, wherein the wax is glyceryl monostearate.

35. The process of claim 33, wherein the wax is stearic acid.

36. The process of claim 29, wherein the water soluble polymer comprises one or more of polyvinylpyrrolidone, hydroxypropyl cellulose, carboxymethylcellulose sodium, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, methyl cellulose, and mixtures thereof.

37. The process of claim 29, wherein the water insoluble polymer comprises one or more of ethyl cellulose, cellulose acetate, methacrylic acid-acrylic acid copolymers with quaternary ammonium groups, and mixtures thereof.

38. The process of claim 29, wherein the alkaline metal salts of higher fatty acids comprise one or more of magnesium stearate, zinc stearate, calcium stearate, and mixtures thereof.

39. The process of claim 38, wherein the alkaline metal salt of higher fatty acid is magnesium stearate.

40. The process of claim 23, wherein the spheroid core includes one or more of pharmaceutically acceptable excipients

41. The process of claim 40, wherein the pharmaceutically acceptable excipient comprises one or more of plasticizers, diluents, colorants or flavoring agents.

42. The process of claim 23, wherein the enteric coating comprises enteric polymers.

43. The process of claim 42, wherein the enteric polymer comprises one or more of hydroxypropyl methylcellulose phthalate, polyvinyl phthalate, cellulose acetate phthalate, copolymers of acrylic and methacrylic acid, and mixtures thereof.

44. The process of claim 42, wherein the enteric coating comprises one or more of alkalizing agents, plasticizer, tack-modifiers and opacifiers.

45. The process of claim 23, wherein the composition is filled into capsules, sachets, or compressed into tablets.

46. A process for the preparation of a controlled release pharmaceutical composition of tamsulosin, the process comprising:

(a) granulating tamsulosin and spheronizing agent with dispersion of one or more of rate controlling polymers to obtain granulates,

(b) extruding the granulates to form extrudates using extruder,

(c) spheronizing the extrudates until spherical cores are formed; and

(d) coating the spherical cores with an enteric polymer.

47. The process of claim 46, wherein the tamsulosin comprises free base, pharmaceutically acceptable salts and isomers of tamsulosin.

48. The process of claim 47, wherein the pharmaceutically acceptable salts of tamsulosin comprise hydrochloride, hydroiodide, hydrobromide, and hydrogen fumarate.

49. The process of claim 48, wherein the pharmaceutically acceptable salt of tamsulosin is a hydrochloride.

50. The process of claim 46, wherein the pharmaceutical composition comprises a concentration of about 0.03% to about 0.33% by weight of tamsulosin.

51. The process of claim 46, wherein the spheronizing agent is microcrystalline cellulose.

52. The process of claim 46, wherein the rate controlling polymer comprises one or more of enteric polymers, water insoluble polymers, water-soluble polymers, alkaline metal salts of a higher fatty acid, waxes, and mixtures thereof.

53. The process of claim 46, wherein the pharmaceutical composition comprises a concentration of about 20% to about 90% by weight of rate controlling polymers.

54. The process of claim 52, wherein the enteric polymer comprises one or more of hydroxylpropylmethyl cellulose phthalate, cellulose acetate phthalate, methacrylic acid and ethyl acrylate copolymer.

55. The process of claim 54, wherein the enteric polymer comprises one or more of methacrylic acid and ethyl acrylate copolymer.

56. The process of claim 52, wherein the wax comprises one or more of hydrogenated vegetable oils, esters of long chain fatty acids, long chain fatty acids, and mixtures thereof.

57. The process of claim 56, wherein the wax is glyceryl monostearate.

58. The process of claim 56, wherein the wax is stearic acid.

59. The process of claim 52, wherein the water soluble polymer comprises one or more of polyvinylpyrrolidone, hydroxypropyl cellulose, carboxymethylcellulose sodium, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, methyl cellulose, and mixtures thereof.

60. The process of claim 52, wherein the water insoluble polymer comprises one or more of ethyl cellulose, cellulose acetate, methacrylic acid-acrylic acid copolymers with quaternary ammonium groups, and mixtures thereof.

61. The process of claim 52, wherein the alkaline metal salts of higher fatty acids comprise one or more of magnesium stearate, zinc stearate, calcium stearate, and mixtures thereof.

62. The process of claim 61, wherein the alkaline metal salt of higher fatty acid is magnesium stearate.

63. The process of claim 46, wherein the spheroid core includes one or more of pharmaceutically acceptable excipients

64. The process of claim 63, wherein the pharmaceutically acceptable excipient includes one or more of plasticizers, diluents, colorants, and flavoring agents.

65. The process of claim 46, wherein the enteric coating comprises enteric polymers.

66. The process of claim 65, wherein the enteric polymer comprises one or more of hydroxypropyl methylcellulose phthalate, polyvinyl phthalate, cellulose acetate phthalate, copolymers of acrylic and methacrylic acid, and mixtures thereof.

67. The process of claim 46, wherein the enteric coating comprises one or more of alkalizing agents, plasticizer, tack-modifiers and opacifiers.

68. The process of claim 46, wherein the composition is filled into capsules, sachets, or compressed into tablets.

69. A method of treating symptoms of benign prostatic hyperplasia, comprising administering a controlled-release pharmaceutical composition of tamsulosin, the composition comprising:

(a) a spheroid core comprising:

i. tamsulosin,

ii. about 10% to about 45% w/w of a spheronizing agent, and

iii. rate controlling polymers, and;

(b) an enteric coating over the spheroid core.

70. A controlled-release pharmaceutical composition comprising one or more individual units comprising:

(a) a spheroid core comprising:

i. tamsulosin,

ii. about 10% to about 45% w/w of a spheronizing agent, and

iii. rate controlling polymers, and;

(b) an enteric coating over the spheroid core.

71. The composition of claim 70, wherein the composition is filled into capsules, sachets, or compressed into tablets.